K113325

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the EVOLUTION® MP Adaptive CS Insert.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 (800) 238-7188
Date:	November 9, 2011
Contact Person:	Danielle Mueller *Regulatory Affairs Specialist II*
Proprietary Name:	EVOLUTION® MP Adaptive CS Insert
Common Name:	Tibial Insert
Classification Name and Reference:	21 CFR 888.3560 Knee joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis Class II 21 CFR 888.3530 Knee joint Femorotibial Metal/Polymer Semi-Constrained Cemented Prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/ JWH, HRY
Predicate Devices:	EVOLUTION® MP Total Knee System ADVANCE® Total Knee System AXIOM® Total Knee System 510(k)s: K894334, K972626, K972770, K033890 K093552, K102380

DEVICE INFORMATION

A. Intended Use

The EVOLUTION® MP Adaptive CS Insert is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Inflammatory degenerative joint disease including rheumatoid arthritis;
3. Correction of functional deformity;
4. Revision procedures where other treatments or devices have failed; and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® Total Knee System is for cemented use only.

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B. Device Description

The purpose of this submission is to introduce a new EVOLUTION® Adaptive CS Tibial Insert that allows use of a femoral component from the EVOLUTION® Total Knee System with a tibial base from the ADVANCE® Knee System. The design features of the EVOLUTION® Adaptive CS Insert are summarized below:

- Tibial inserts manufactured from UHMWPE
- Available in 11 sizes, left and right
- Tibial insert thickness: 10 – 20mm

The EVOLUTION® Adaptive CS Insert was evaluated via mechanical testing and engineering analyses; including static stability, contact area, and range of motion testing. A review of these results indicates that the subject device is equivalent to predicate devices and is capable of withstanding expected *in vivo* loading without failure.

C. Substantial Equivalence Information

The indications for use of the EVOLUTION® Adaptive CS Insert are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the EVOLUTION® Adaptive CS Insert are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technologies, Inc.
% Ms. Danielle Mueller
Regulatory Affairs Specialist II
5677 Airline Road
Arlington Tenessee 38002

DEC - 9 2011

Re: K113325
Trade/Device Name: EVOLUTION® MP Adaptive CS Insert
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, HRY
Dated: November 9, 2011
Received: November 10, 2011

Dear Ms. Mueller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113325

Indications for Use

510(k) Number (if known):

Device Name: EVOLUTION® MP Adaptive CS Insert

Indications For Use:

The EVOLUTION® MP Adaptive CS Insert is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Inflammatory degenerative joint disease including rheumatoid arthritis;
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The EVOLUTION® Total Knee System is for cemented use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113325